Meeting Minutes, Open Session, Drug Utilization Review Board July 8, 2020		
Drug Utilization Review Board *Due to COVID-19, this meeting was held virtually.	**DUR Board Members:** Moneeshindra Mittal, MD, Chair James Backes, PharmD, Interim Chair Jennifer Clair, MD Katie Burenheide Foster, PharmD, MS, BCPS, FCCM (absent) Kristen Powell, PharmD LaTonyua Rice, PharmD, BCGP Arthur Snow, MD Serena Stutzman, APRN Roger Unruh DO **KDHE/DHCF/Contractor Staff:** Annette Grant, RPh. Victor Nguyen, PharmD Carol Arace, Sr. Admin. **DXC Technology Staff/KEPRO Staff** Karen Kluczykowski, RPh Kathy Kaesewurm, RN, BSN Ariane Casey, PharmD Harry Vu, PharmD **MCO Staff:** Jan Mueller, RPh, UnitedHealthcare Community Plan Alan Carter, PharmD, Aetna Better Health of Kansas Angie Yoo, PharmD, Sunflower State Health Plan	**Public Attendees**: Atul Patel, KC Bone & Joint; Brad Brekke, Coherus; Brent Hildebrand, Gilead; Brent Young, Global Blood Therapeutics; Cheryl Donahue, Tracy Copeland, Leslie Zanetti, Sarepta; Chris Beal; Daren Grothe, Dave Miley, Teva; Donna Osterlund, Sanofi; Erin Hohman, Janssen; Gina Heinen, Mary Shefchyk, Ryan Flugge, Novo Nordisk; Janie Huff, Tricida; Jason Todd Dickerson, Jazz Pharma; Jean Ritter, Zealand Pharma; Jeff Knappen, Sparks; Jim Baumann, Rob Hansen, Phil King, Pfizer; Karen Floeder, Chelsea Leroue, Biohaven Pharmaceuticals; Katelin Lucariello; Keith Rose, Biocodex; Kelly Maynard; Kevin Duhrkots, Sanofi Genzyme; Kim Walter, Johnson & Johnson; Kristi Kemp, Allergan; Laura Hill, Melissa Basil, Patricia Jacob, AbbVie; Lucy Hernandez, Horizon Therapeutics; Marc Parker, Sunovion; Mary Nelson, Susan Zalenski, Johnson & Johnson; Rhonda Clark, Indivior; Ricki Roberson, Merck; Scott Donald, Tanner Bain, KEPRO; Sean Jones, Takeda; Seth Bernstein; Shannon Meyer; Shannon Wilhelm; Janssen; Tami Sova, Biogen; Tony Salicos, Greenwich Biosciences

TOPIC	DISCUSSION	DECISION
I. Call to Order	Dr. Mittal called the meeting to order at 10:06 a.m.	
Announcements and Introductions	The meeting operator informed everyone of her role and the process for the meeting. Dr. Mittal asked the state for any announcements. The state responded that the January and July meetings come quickly after a holiday and that with extra days off at those times of the year, it is sometimes difficult to have enough time to prepare for those two meetings. The state asked the Board if changing the week of the month to every third Wednesday would cause any hardship. The start date proposed was January 2021. **Board Discussion:** Dr. Backes mentioned that since enough lead time was given, that would be fine for him. Dr. Mittal was ok with it but asked that the state send this request in an email to the Board to see if most of the Board was accepting to this. The state will send an email to the Board. No vote is needed.	
II. Old Business **A. Review and Approval of January 8, 2020 Meeting Minutes**	**Board Discussion:** Dr. Mittal asked if there were any amendments/changes to the minutes requested. Dr. Casey, KEPRO, mentioned that the calendar year should be 2020 instead of 2019. The amendment was made.	Dr. Snow moved to approve the minutes, as amended. Dr. Unruh seconded the motion. The motion was approved, unanimously.
III. New Business **A. New Preferred Drug List (PDL) Classes** 1. Acne Agents- Isotretinoin Products	**Background:** At the March 2020 PDL meeting, the committee approved the addition of Acne Agents - Isotretinoin Products to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents. **Public Comment: None** **Board Discussion: None**	Dr. Clair moved to approve. Dr. Snow seconded motion. The motion was approved unanimously.

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2. Colchicine Products- Gout Prophylaxis	**Background:** At the March 2020 PDL meeting, the committee approved the addition of Colchicine Products - Gout Prophylaxis to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents. **Public Comment:** None. **Board Discussion:** Dr. Mittal asked if these products are biosimilar, which the state inferred as meaning, clinically equivalent, and responded with yes. Dr. Powell asked which ones are non-preferred. The state said those decisions would be made by the state. Dr. Mittal mentioned that the Board reviews requests for new PDL classes, which the state can then manage the agents within.	Dr. Powell motioned to approve. Dr. Snow seconded motion. The motion was approved unanimously.
3. SGLT2 Inhibitor/DPP-4 Inhibitor/Biguanide	**Background:** At the March 2020 PDL meeting, the committee approved the addition of SGLT2 Inhibitor/DPP-4 Inhibitor/Biguanide to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents. **Public Comment:** None. **Board Discussion:** Dr. Mittal asked about the availability of both agents. The state said that both agents have been FDA approved and so they are being proactive in creating this PDL class, which increases the potential for rebates. Sometimes it takes a little time for agents to be on the market once approved by the FDA. S. Stutzman, APRN, said that she was for saving the state money.	Stutzman, APRN motioned to approve. Dr. Rice seconded motion. The motion was approved unanimously.

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4. Consent Agenda Item- Biosimilars	**Background:** At the March 2020 PDL meeting, the committee approved to further expand the PDL Consent Agenda Criteria. Biosimilars having the same FDA-approved indication as the reference drug may be added using this process. **Public Comment:** None. **Board Discussion:** The state explained the PDL Consent Agenda Item history and process. Dr. Mittal confirmed with the state that the only criteria in this process being voted on today was the last item #6, biosimilars. All items #1-5 were previously approved.	Dr. Unruh moved to approve. Dr. Stutzman seconded the motion. The motion was approved unanimously.
B. Mental Health Medication Advisory Committee (MHMAC) 1. Antidepressant Medications – Safe Use for All Ages	**Background:** At the February 2020 MHMAC meeting, the committee revised the criteria for use of Antidepressant Medications – Safe Use for All Ages prior authorization (PA), to include Spravato® and include the PHQ-9 depression rating scale. **Public Comment:** Erin Hohman from Janssen Pharmaceuticals spoke to being available for questions, if the Board had any. **Board Discussion:** The state explained that there were two MHMAC meetings prior to this DUR Board meeting, due to the April DUR Board meeting being cancelled. The Board will review each update in order of MHMAC approval. The state reviewed the changes made to this PA since the last DUR Board review. Dr. Mittal reminded the committee that all items from the MHMAC are to be either approved or denied as is and cannot be amended by the DUR Board.	Dr. Backes moved to approve. Dr. Powell seconded the motion. The motion was approved unanimously.

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2. Antidepressant Medications – Safe Use for All Ages	**Background:** At the May 2020 MHMAC meeting, the committee further revised the criteria for use of Antidepressant Medications – Safe Use for All Ages PA to include a dosing table. **Public Comment:** None. **Board Discussion:** The state reviewed the changes made at the May MHMAC meeting. Dr. Mittal asked about items in the table that are a different color. The state said those items came from committee member suggested changes that were made. Some doses were allowed because the drug can be used for other indications and we did not want to inhibit that option. Dr. Powell asked about the pediatric column that says not approved. Would that be subject to prior authorization? The state said that there is a place on the PA form for written peer-to-peer review, for compelling reasons for approval, used for plan psychiatrist review/discussion with the provider.	Dr. Backes moved to approve. Dr. Powell seconded the motion. The motion was approved unanimously.
3. Antipsychotic Medications - Safe Use for All Ages	**Background:** At the February 2020 MHMAC meeting, the committee revised the criteria for use of Antipsychotic Medications – Safe Use for All Ages PA to include Secuado® and Caplyta®. Step therapy was also revised. **Public Comment:** None **Board Discussion:** The state reviewed all the changes made at the February MHMAC meeting. There was a question if these were "me too" agents. The state said that one was and the other was not, and what the differences were.	Dr. Clair moved to approve. Stutzman, APRN seconded the motion. The motion was approved unanimously.

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4. ADHD Medications – Safe Use for All Ages	**Background:** At the May 2020 MHMAC meeting, the committee revised the criteria for use of ADHD Medications – Safe Use for All Ages PA to include Adhansia XR™. **Public Comment:** None **Board Discussion:** The state reviewed the changes to the PA since last time. Dr. Mittal asked if the Consent Agenda Item process would have allowed this drug to be added. The state said only for the PDL Program and that any changes to the clinical PA criteria have to be brought before the Board.	Dr. Unruh moved to approve. Dr. Powell seconded the motion. The motion was approved unanimously.
5. RDUR Criteria – Further Review	**Background:** At the May 2020 MHMAC meeting, the committee approved Retrospective Drug Utilization Review (RDUR) criteria for mental health medications. Patients taking multiple concurrent mental health medications will be reviewed on a regular basis. These criteria indicate the need for further review with a plan psychiatrist. **Public Comment:** None **Board Discussion:** The state explained that sometimes there are drug regimens that could be within the PA criteria limits for all drug classes but fall outside of standards for total numbers of mental health drugs and questionable prescribing patterns. The state did not want to have an edit at the point of sale but rather have a post claims review. The RDUR criteria presented were approved by the MHMAC to use in the RDUR process. The state explained at a high level, a case that they were presented with, that would fall into this scenario. It is important that if a patient is to be on several mental health drugs, that a psychiatrist be consulted for maximum drug benefit/use and minimum side effects. Dr. Mittal asked if the criteria was for all medications and the state said just for mental health medications.	Stutzman, APRN moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.

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	Dr. Mittal asked how many members fell within these criteria and if patients who are institutionalize were included. The state said yes and presented some data. This is for all patients, all settings. Even patients in high level facilities may not have proper drug regimens. Depending on several factors, some patients may not have psychiatrists overseeing their care, at all times. This is also an education opportunity for the providers. Dr. Powell asked if the data represents maintenance and as needed medications. Benzodiazepines could go either way. The state had pulled cases, looked for patterns, and mainly looked at drug use for greater than 60 days. Dr. Powell asked about the inpatient to outpatient transition and that impact. The state said that the patient needs to be on a drug for greater than 60 days and this is a manual review process, so all pertinent factors will be considered. Dr. Powell said that sometimes the regimen for inpatients may not be in line with the PA criteria and so when they become outpatients, that creates some issues. The state confirmed that this has been a concern of several MHMAC members. This review will also help us to find patterns of prescribing and of prescribers. That it is not enough to get the patient stable, but to get them to a proper drug regimen while they are still inpatient status.	
C. Prioritized Agenda Items 1. Migraine – Prophylaxis Agents – New PA Criteria	**Background:** **Migraine – Prophylaxis Agents –** New PA Criteria These criteria will combine and supersede the criteria for Botulinum Toxins, the CGRP Antagonists, and the Topiramate ER criteria for agents used for the prophylaxis of migraines. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information, clinical guidelines, and step therapy. **Public Comment:** None **Board Discussion:** None.	Dr. Clair moved to approve. Dr. Snow seconded the motion. The motion was approved unanimously.

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2. Botulinum Toxins – Revised PA Criteria	**Background:** This revision modifies PA criteria to carve out the migraine indications. A separate PA criterion for migraine prophylaxis will be created. Indication updates were made to Botox®, Myobloc®, and Myobloc®. **Public Comment:** None. **Board Discussion:** None.	Dr. Powell moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
3. Migraine – Acute Treatment Agents – New Criteria	**Background:** Multiple new agents now exist for the acute treatment of migraines. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information, clinical guidelines, and step therapy. **Public Comment:** Dr. Atul Patel, KC Bone & Joint introduced himself and his practice setting. His focus has been on getting patients from being disabled from migraines and getting them back to work. Triptans are a good starting drug. His experience with Ubrelvy has been helpful for those whom Triptans do not provide enough relief. Also, had comments on migraine scoring scales. Patricia Jacob from AbbVie spoke to Ubrelvy. This agent is non-controlled and other drug benefits compared to other migraine treatment options. Ms. Jacob requested that primary care physicians be allowed to prescribe Ubrelvy. Chelsea Leroue from Biohaven Pharmaceuticals spoke to Nurtec ODT. Ms. Leroue agreed with comments from other speakers and appreciated that the state's proposed criteria are in accordance with the AHS guidelines. Quantity limits to address the blister pack we requested. **Board Discussion:** Dr. Clair asked about changing the MTOQ score to possibly use MIDAS instead. Dr. Casey said that the studies showed both but that we would be accepting to that change. The American Headache Society does still	Dr. Powell moved to approve, as amended. Dr. Snow seconded the motion. The motion was approved unanimously.

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	recommend two oral Triptans. Dr. Powell was in agreemenet with a different scoring tool. Dr. Mittal asked Dr. Patel for recommendations of scoring tools. Dr. Casey showed tools mentioned in the literature. Dr. Mittal asked the state if they had written down the public requests and wanted to review them. The state reviewed those requests: the first was one vs two Triptans for pre-requisite drugs. The state recommended going with the guidelines because guidelines are what we are using to guide our PA criteria development in general. The second request was a change of scoring tool or to remove it from the criteria. The recommendation was to find another acceptable tool from the choices shown. The third request was quantity limits. Lastly, whether specialists should be required, or primary physicians allowed to prescribe. Dr. Nguyen made a point that the previous Triptan trial is only for two weeks each drug, so that is something to consider. Dr. Patel gave some provider suggestions. Dr. Nguyen commented that requiring a specialist was proposed because we wanted to rule out any underlying causes of migraines that could be more serious. Dr. Patel said that neurologist is a broader heading so that should catch the recommendations that he had. The state said that revisiting this part in the future for potential updates could be done. The Board agreed to table this item until later in the meeting, to allow for the scoring tool section and corresponding table to be updated. Later, the MIDAS scoring tool and score was added to the PA. Dr. Powell clarified whether the number of tablets for Nurtec ODT was to be changed. Dr. Casey said that going with the limit of number of migraines, would fall in line with the table as listed. Dr. Powell commented about a patient having more than four migraines per month, might move to prevention treatment. Dr. Casey confirmed this was the intention.	
4. Type 2 Diabetes Mellitus (T2DM) Agents – Revised PA Criteria	**Background:** This revision modifies PA criteria to combine and supersede the Metformin ER and Diabetic Agents criteria and update to the new PA format. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and clinical guidelines. **Public Comment:** Erin Hohman from Janssen Pharmaceuticals commented on chart and the eGFR limitations.	Dr. Powell moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.

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	Ryan Flugge from Novo Nordisk did not have any concerns with the Rybelsus criteria and was available for questions from the Board. **Board Discussion:** The state noted that the comment made on the chart has a strike through and showed what the "clean copy" PA would look like, showing that part removed.	
5. Opioid Products Indicated for Pain Management – Revised Criteria	**Background:** This revision modifies PA criteria to clarify that active pharmaceutical ingredients (APIs) are not managed on this PA criteria. This also clarifies that the considerations for MME calculations generally exclude injectables and cough/cold products that contain opioids, similar to the CDC's inclusion and exclusion criteria. **Public Comment:** None. **Board Discussion:** None.	Stutzman, APRN moved to approve. Dr. Snow the motion. The motion was approved unanimously.
6. Duchenne Muscular Dystrophy (DMD) Agents – New Criteria	**Background:** These criteria will combine and supersede the Emflaza® and Exondys 51® criteria for agents used for the treatment of Duchenne muscular dystrophy. These prior authorization criteria include step therapy, adds Vyondys 53™, and are being proposed to ensure appropriate use based upon the FDA-approved labeling information and clinical guidelines. **Public Comment:** None. **Board Discussion:** None.	Dr. Snow moved to approve. Stutzman, APRN seconded the motion. The motion was approved unanimously.

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7. Advanced Medical Hold Manual Review (AMHMR) – Revised Criteria	**Background:** This revision is to update the drug selection group in the Manual Guidelines section. **Public Comment:** None. **Board Discussion:** Dr. Mittal asked if drugs meeting these criteria are managed forever through this option. The state said that only for up to 12 months, which gives the state time to determine if permanent criteria are needed or if the current management method should be discontinued.	Dr. Rice moved to approve. Dr. Clair seconded the motion. The motion was approved unanimously.
8. Fee-for-Service Retrospective Drug Utilization Review Topic Selections	**Background:** The DUR Board will select topics, for the two (2) FFS RDUR interventions between July and September 2020. **Public Comment:** None. **Board Discussion:** Dr. Mittal recapped the four RDUR proposals given by Dr. Casey from KEPRO and that the Board needs to choose two of the four choices. Dr. Clair suggested the HIV drug use topic because if someone is under-dosed that is a patient risk. Also, they are expensive medicines that we would want to have good results with. Dr. Powell agreed. Improving adherence ultimately decreases health system costs later. Dr. Powell suggested the PPI topic because it has a higher number of patients impacted but also, she has seen this as an issue even in kids. Dr. Mittal asked if we made changes in the last year. The state said that they did remove the clinical PA for PPIs last year but there are still quantity limit type edits still active through policy. Dr. Casey said that this data pull was for Fee for Service only and that makes it more difficult to find issues with a high number of patients. However, at the provider level, any change would also impact the Managed Care population. The Board chose the topics: long term use of proton pump inhibitors and HIV drug underuse.	Dr. Rice moved to accept the two topics chosen. Dr. Powell seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION
D. Additional Agenda Items (as time allows) **1.** Minimum Requirements Prior Authorization – Updated Drug List	**Background:** This revision adds the following agents: Arikayce®, Epidiolex®, Onfi®, Sympazan™, Neudexta®, Viberzi™, Increlex®, Ofev®, Osphena®, Esbriet®, Banzel®, Vesicare LS™, Diacomit®, and Xermelo™ **Public Comment:** Keith Rose from Biocodex stated that he was open for any questions from the Board. **Board Discussion:** Dr. Mittal asked if any of these agents are on any other PA. Dr. Casey confirmed that they are not. The state added that this is a simple way to manage high dollar drugs that we do not want to have a separate PA for but want to make sure that we are not allowing off-label uses where we should not be. Carol mentioned that she got an email about a possible table information concern. The questioned item was reviewed. Dr. Casey showed that the item was listed and correct but was on the next line and the reviewer may have missed that line.	Stutzman, APRN moved to approve. Dr. Powell seconded the motion. The motion was approved unanimously.
2. Atopic Dermatitis (AD) Agents – Revised Criteria	**Background:** This revision modifies PA criteria to clarify the use of conventional agents and to update indications for Eucrisa® and Dupixent®. **Public Comment:** Phil King from Pfizer noted that the criteria were up to date according to their most recent FDA approvals and support the criteria as listed. He would be happy to answer any questions. **Board Discussion:** None	Dr. Unruh moved to approve. Dr. Powell seconded the motion. The motion was approved unanimously.

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3. Codeine Products in Children	**Background:** Request for an age limitation edit at the point-of-sale for codeine products used in children. **Public Comment:** None. **Board Discussion:** None.	Stutzman, APRN moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.
4. Ulcerative Colitis (UC) Agents – Revised Criteria	**Background:** This revision modifies PA criteria to adjust step therapy for Xeljanz®/Xeljanz® XR, add Stelara®, and to add the biosimilars Abrilada™ and Avsola™. **Public Comment:** Phil King from Pfizer noted that the criteria were according to package insert and had no concerns. He would be happy to answer any questions. Erin Hohman from Janssen Pharmaceuticals stated that she had no specific comments to the criteria but was available for questions. **Board Discussion:** None.	Dr. Clair moved to approve. Dr. Snow seconded the motion. The motion was approved unanimously.
5. Plaque Psoriasis (PsO) Agents – Revised Criteria	**Background:** This revision modifies PA criteria to update changes to Taltz™ indication and add biosimilars Hadlima™, Abrilada™, and Avsola™. **Public Comment:** None. **Board Discussion:** None.	Dr. Powell moved to approve. Dr. Snow seconded the motion. The motion was approved unanimously.

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6. Hepatitis C Agents – Revised Criteria	**Background:** This revision modifies PA criteria to update changes to Epclusa® indication, clarify treatment experience for Sovaldi® and Harvoni®, and add NS5A testing for Zepatier®. **Public Comment:** None. (Brent Hildebrand from Gilead called in on the MS Agents PA comment time to state that he tried to call in for the Hep-C PA comment time but there was a delayed entry into the system.) **Board Discussion:** None.	Dr. Clair moved to approve. Dr. Snow seconded the motion. The motion was approved unanimously.
7. Multiple Sclerosis (MS) Agents – Revised Criteria	**Background:** This revision modifies PA criteria to update changes to Glatopa® dosing, and add two additional FDA-approved agents, Bafiertam® and Zeposia®. **Public Comment:** Brent Hildebrand from Gilead called in on the MS Agents PA to state that he tried to call in for the Hep-C PA comment time but there was a delayed entry into the system. (No comment on MS Agents PA.) **Board Discussion:** None.	Dr. Unruh moved to approve. Dr. Snow seconded the motion. The motion was approved unanimously.
IV. Open Public Comment	None.	
V. Adjourn	The meeting adjourned at 12:44 p.m.	Stutzman, APRN moved to adjourn. Dr. Rice seconded the motion. The motion to adjourn was approved unanimously.

The next DUR Board meeting is scheduled for October 14, 2020.

All approved PA criteria are posted to the KDHE website- http://www.kdheks.gov/hcf/pharmacy/pa criteria.htm